

Appl. No. 10/036,308

Amendment dated June 24, 2004

Reply to Advisory Action dated May 20, 2004 and Office Action dated December 24, 2003

This listing of claims will replace all prior versions and listings of claims in the application:

Listing of Claims:

1-3. (Cancelled)

4. (Previously presented) A method for diagnosing Alzheimer's disease comprising:

- (a) obtaining blood or cerebrospinal fluid from a subject;
- (b) detecting the amount of human kallikrein 6 ("hK6") in said blood or cerebrospinal fluid; and
- (c) comparing said amount of hK6 detected to an amount for healthy control subjects, where detection of a statistically significant increase of hK6 compared with an amount for the healthy control subjects is indicative of Alzheimer's disease.

5. (Currently amended) A method for diagnosing Alzheimer's disease as claimed in claim 4 comprising:

- (a) contacting the blood or cerebrospinal fluid with an antibody specific for hK6 which is directly or indirectly labelled with a detectable substance;
- (b) detecting the amount of hK6 by detecting measuring the amount of the detectable substance in the blood or cerebrospinal fluid;
- (c) comparing the amount of hK6 to an amount obtained for samples from healthy control subjects where a statistically significant increase in the amount of hK6 compared with the amount for the healthy control subjects is indicative of Alzheimer's disease.

6. (Currently amended) A method for the diagnosis of Alzheimer's disease as claimed in claim 4 comprising

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- (a) incubating the blood or cerebrospinal fluid with a first antibody specific for hK6 which is directly or indirectly labeled with a detectable substance, and a second antibody specific for hK6 which is immobilized;
- (b) separating the first antibody from the second antibody to provide a first antibody phase and a second antibody phase;
- (c) detecting the ~~amount of~~ hK6 by ~~detecting~~ measuring the amount of the detectable substance in the first or second antibody phase; and
- (d) comparing the amount of hK6 with an amount obtained for samples from healthy control subjects where a statistically significant increase in the amount of hK6 levels compared with the amount for the healthy control subjects is indicative of Alzheimer's disease.

7-8. (Cancelled)

9. (Previously presented) A method as claimed in claim 6 wherein in step (a) the first and second antibodies are contacted simultaneously or sequentially with the blood or cerebrospinal fluid.

10. (Previously presented) A method as claimed in claim 5 wherein the antibody is a monoclonal antibody, a polyclonal antibody, immunologically active antibody fragments, humanized antibody, an antibody heavy chain, an antibody light chain, a genetically engineered single chain F_v molecule, or a chimeric antibody.

11. (Previously presented) A method as claimed in claim 5 wherein the detectable substance is alkaline phosphatase.

12. (Previously presented) A method as claimed in claim 11 wherein the alkaline phosphatase is detected using a fluorogenic substrate.

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13. (Previously presented) A method as claimed in claim 12 wherein hK6 is detected using time-resolved fluorescence.